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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/522,230	01/24/2005	Taeun Park	1751-367	7022

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EXAMINER	
VU, JAKE MINH	

ART UNIT	PAPER NUMBER
1618	

DATE MAILED: 09/26/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/522,230	PARK ET AL.	
	Examiner	Art Unit	
	Jake M. Vu	1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *24 January 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-15* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-15* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Receipt is acknowledged of Applicants' Information Disclosure Statement and Amendment filed on 01/24/05. Claims 1-15 are pending in the instant application.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

Claims 11, 14, and 15 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 11 is indefinite, because it is unclear what content is referring to in "wherein a content of the 3% by weight".

Claim 14 is indefinite, because it is unclear what quantity is "at least 10 by weight." What is the unit? Is it percentage? Please clarify.

Claim 15 is indefinite, because it is unclear what quantity is "at least 0.5 by weight." What is the unit? Is it percentage? Please clarify.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Claims 1, 3, and 4 are rejected under 35 U.S.C. 102(a) as being clearly anticipated by Taketoshi et al (JP 2001278810).

Applicants' claims are directed towards a composition hybrid of a drug with a layered silicate, such as montmorillonite, and a poorly water-soluble drug being selected from a group consisting of itraconazole, cyclosporine, and carvedilol. Taketoshi disclosed a blended composition comprising of montmorillonite and cyclosporine. (See abstract and MEANS category)

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Taketoshi et al (cited supra).

Instant claims are directed toward a method for making and a hybrid composition comprising a layered silicate and a drug selected from a group consisting of cyclosporine, itraconazole, and carvedilol.

Taketoshi teaches a method for making a hybrid composition comprising a layered silicate and a cyclosporine by mixing an aqueous solution, an organic solution, the layered silicate, and cyclosporine (see MEANS category). Taketoshi teaches to

dissolve the poorly water-soluble drug in an organic solvent such as, methanol, ethanol, etc., describing "the water-soluble organic solvent of this invention means the **organic solvent** classified according to the method of examining the **solubility** specified to a Japanese pharmacopoeia for 'being very easy to melt' and 'being easy to melt' **to water**."

Additionally, Taketoshi teaches: to dissolve the layered silicate in water with a pH of 5-6 or less; the amount of layered silicates used are usually 0.01% to 10% compared to the whole pharmaceutical preparation; the amount of drug is the composition is 0.01-10% or an amount efficient for a drug effective dose; the drug to silicate ratio is 10:1 – 1:100; and additional excipients may be added for desired result, such as hydroxypropyl methyl cellulose.

Taketoshi does not specifically teach using itraconazole as the poorly water-soluble drug or to use Eudragit E100® as an excipient. However, It would have been obvious to incorporate itraconazole as the hydrophobic drug and Eudragit E100® and expect success, because Taketoshi teaches to use poorly water-soluble drugs. Itraconazole is a poorly water-soluble drug as disclosed by Applicants' Specification. In addition, hydroxypropyl methylcellulose and Eudragit E100® is known in the prior art (US 6,248,363, col. 42, line 28-30) as possible excipients in compositions of poorly water-soluble drugs such as itraconazole (US 6,248,363, col. 1, line 16); thus, a person of ordinary skill in the art would routinely use different polymers of Eudragit to get the desired result.

Telephonic Inquiries

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jake M. Vu whose telephone number is (571) 272-8148. The examiner can normally be reached on Mon-Fri 8:30AM-5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page can be reached on (571) 272-0602. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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Art Unit 1618

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